

UNITED STATES OF AMERICA

v.

1:23CR 326-1

WENDELL LEWIS RANDALL

The Grand Jury charges:

Background

At all times relevant hereto:

- 1. WENDELL LEWIS RANDALL was a physician licensed to practice medicine by the State of North Carolina.
- 2. WENDELL LEWIS RANDALL owned and worked as the sole physician at his medical practice, the National Institute of Toxicology, PLLC ("NIT"), where he provided pain management services, located in Surry County, North Carolina, within the Middle District of North Carolina.

The Controlled Substances Act

The Controlled Substances Act, 21 U.S.C. §§ 801, et seq. (the 3. "CSA"), governed the manufacture, distribution, and dispensation of controlled substances in the United States, including narcotics that were prescribed by physicians. The CSA established certain drugs and substances as "controlled substances," which were assigned to one of five schedules, Schedule I, II, III,

IV, or V, depending on the drugs' potential for abuse, likelihood of physical or psychological dependency, and accepted medical use.

- 4. Controlled substances in Schedule II are those with a currently accepted medical use in treatment in the United States and that have a high potential for abuse—abuse that could lead to severe physical or psychological dependence. Oxycodone, oxymorphone, hydrocodone, and amphetamine are examples of Schedule II narcotics.
- 5. The CSA defined the term "distribute" to mean the delivery of a controlled substance or listed chemical, whether by actual, constructive, or attempted transfer of a controlled substance or listed chemical.
- 6. Medical practitioners, such as physicians and nurse practitioners, who were authorized to prescribe controlled substances by the jurisdiction in which they were licensed to practice medicine were authorized under the CSA to prescribe, or otherwise distribute, controlled substances, if they were registered, or exempt from registration, with the Attorney General of the United States. 21 U.S.C. § 822(b); 21 C.F.R. § 1306.03. Upon application by the practitioner, the Drug Enforcement Administration ("DEA") assigned a unique registration number to each qualifying medical practitioner, including physicians and nurse practitioners.

- 7. Chapter 21 of the Code of Federal Regulations, Section 1306.04, governed the issuance of prescriptions and provided, among other things, that a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."
- 8. At NIT, WENDELL LEWIS RANDALL accepted cash-paying patients and insurance patients, including private and public insurance, such as Medicare and Medicaid.

Medicare, Medicaid, and Urine Drug Tests

- 9. The United States Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS"), was an agency of the United States that administered the Medicare and Medicaid programs. Medicare was a federally funded health insurance program that provided insurance coverage for persons aged 65 or over and to persons under the age of 65 who are entitled to benefits due to disability. Medicare was a "health care benefit program" as defined by Title 18, United States Code, Section 24(b).
- 10. The North Carolina Medicaid Program ("Medicaid") was a state administered program aided by federal funds and was a "health care benefit program" as defined by Title 18, United States Code, Section 24(b). Medicaid provided health insurance coverage to certain categories of low-income

individuals, including children, pregnant women, parents of eligible children, and people with disabilities, referred to as "beneficiaries."

- 11. In North Carolina, Medicaid was administered by the North Carolina Department of Health and Human Services Division of Health Benefits ("DHB").
- 12. Among a variety of items and services, both Medicare and Medicaid provided coverage to beneficiaries for outpatient physician services, such as laboratory services like urine drug testing ("urine testing").
- 13. Medical service providers, including clinics and physicians ("service providers"), meeting certain criteria, could enroll in and obtain Medicare and Medicaid provider numbers. Upon Medicare and Medicaid enrollment, service providers were permitted to provide medical services and items to beneficiaries and members, and subsequently submit claims, either electronically or in hardcopy, to Medicare and Medicaid, through fiscal intermediaries, seeking reimbursement for the cost of services and items provided.
- 14. When seeking reimbursement from Medicare and Medicaid, service providers certified that: (1) the contents of the claim forms were true, correct, and complete; (2) the claim forms were prepared in compliance with the laws and regulations governing Medicare and Medicaid; and (3) the

services purportedly provided, as set forth in the claim forms, were medically necessary.

- 15. Medicare and Medicaid reimbursed claims submitted by service providers if the services and items provided were medically necessary for the diagnoses and treatment of beneficiaries. Conversely, Medicare and Medicaid did not cover and would not reimburse claims for services and items that were not medically necessary.
- 16. WENDELL LEWIS RANDALL was enrolled as a provider with both Medicare and Medicaid, and was assigned National Provider Identifier ("NPI") 1902856065 by CMS. NIT conducted business through NPI 1558766501.
- 17. When seeking reimbursement from Medicare and Medicaid, service providers submitted the cost of the service or item provided together with the appropriate "procedure code," as defined by the American Medical Association, and set forth and maintained in the Current Procedural Terminology ("CPT") Manual or by the Healthcare Common Procedure Coding System ("HCPCS"). Although service providers submitted the cost of the service provided, together with other information, Medicare and Medicaid reimbursed providers designated amounts according to the CPT or HCPCS code utilized.

- 18. Urine testing was divided into two categories: presumptive (qualitative) testing and definitive (quantitative or confirmation) testing. Presumptive testing identified which substances, if any, were present in the provided specimen. Definitive testing identified how much of a particular substance was present in the provided specimen.
- 19. Presumptive testing was performed in a variety of ways, including utilizing devices that were capable of being read by direct optical observation, such as "cups" that reacted to the specimen and identified which drugs, if any, were present ("optical devices"), as well as by more complex testing performed by instrument chemistry analyzers.
- 20. Definitive testing was necessarily performed by higher complexity instrument chemistry analyzers.
- 21. Medicare and Medicaid considered presumptive testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients, provided the presumptive testing was used in the diagnosis and treatment of beneficiaries and members and the need for the testing was substantiated by documentation in the patient's medical record. Conversely, Medicare and Medicaid specifically excluded from coverage, and did not consider medically necessary, "blanket orders" or routine presumptive testing of substances.

- 22. Medicare and Medicaid considered definitive testing to be medically necessary, and appropriately reimbursable, in the treatment of chronic pain patients in certain limited circumstances, including when beneficiaries or members had a specific and documented need for definitive testing. Conversely, Medicare and Medicaid specifically excluded from coverage, and did not consider medically necessary, "blanket orders" or routine definitive testing of substances.
- 23. Definitive drug testing was reported with HCPCS codes G0480, G0481, G0482, and G0483. These codes differed based on the number of drug classes, including metabolites, tested, and were reimbursed at different rates—the more drugs tested, the greater the reimbursement.

COUNTS ONE THROUGH EIGHT (Health Care Fraud)

- 24. Paragraphs 1 through 23 of this Indictment are realleged and incorporated by reference as though fully set forth herein.
- 25. Beginning at least in or about August 2018, and continuing through at least in or about December 2021, in the County of Surry, in the Middle District of North Carolina, WENDELL LEWIS RANDALL aided and abetted by others known and unknown to the Grand Jury, in connection with the delivery of and payment for health care benefits, items, and services, did

knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in 18 U.S.C. § 24(b), that is, Medicare, Medicaid, and obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of said health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services.

Purpose of the Scheme

26. It was a purpose of the scheme for WENDELL LEWIS RANDALL to unlawfully enrich himself and NIT by, among other things, submitting and causing the submission of false and fraudulent claims to Medicare and Medicaid.

The Manner and Means of the Scheme

- 27. The manner and means by which the defendant, WENDELL LEWIS RANDALL, sought to accomplish the object of the scheme included, among others, the following:
- a. NIT maintained an analyzer capable of performing higher-complexity definitive testing ("definitive analyzer").

- b. WENDELL LEWIS RANDALL formed NIT for the purpose of acquiring and maintaining the definitive analyzer so that he could provide laboratory services, specifically, urine testing, to beneficiaries and others;
- c. In or about August 2018, WENDELL LEWIS RANDALL acquired and installed the definitive analyzer on the premises of NIT for the purpose of performing definitive testing;
- d. WENDELL LEWIS RANDALL, through NIT, provided medical practitioner services to beneficiaries and others, including purported pain management services by, among other methods, prescribing controlled substances, namely opioids ("opioid treatment");
- e. For each patient office visit, WENDELL LEWIS RANDALL directed NIT employees to supply urine testing cups to beneficiaries and others for the purpose of having these individuals provide urine samples suitable for urine testing ("provided specimen");
- f. WENDELL LEWIS RANDALL directed NIT employees to perform definitive testing on every provided specimen, irrespective of any identified individualized need, and concealed the existence of this blanket order from health care benefit programs;
- g. At WENDELL LEWIS RANDALL's order and direction, employees of NIT submitted false and fraudulent claims to Medicare and

Medicaid for G0483, the highest code for definitive testing, representing that these tests were medically necessary for the diagnosis and treatment of beneficiaries, members, and others, when, in reality, as WENDELL LEWIS RANDALL then well knew, there was no medical necessity for these tests and these tests were performed for the purpose of maximizing subsequent reimbursements from Medicare and Medicaid.

h. From August 2018 through December 2021, WENDELL LEWIS RANDALL, through NIT, billed Medicare and Medicaid more than \$4.5 million for the fraudulent definitive testing.

Acts in Execution of the Scheme

28. In order to execute and attempt to execute a scheme to defraud and to obtain money and property, and to accomplish the object of the scheme, WENDELL LEWIS RANDALL committed, caused others to commit, and aided and abetted others in committing the following acts within the Middle District of North Carolina, that is, on or about the dates listed below, WENDELL LEWIS RANDALL, caused the following false and fraudulent claims to be submitted to Medicare and Medicaid for G0483, and aided and abetted in the submission of such claims, which claims indicated that the urine testing provided had been performed and was medically necessary when, in fact, as

WENDELL LEWIS RANDALL knew, the definitive tests were not medically necessary:

Count	Beneficiary	Submission Date	Claim Number	Paid Date	Claim Amount Paid
1	S.R.	11/23/2018	Medicaid 1832704204120000	11/27/2018	\$195.86
2	S.R.	11/23/2018	Medicaid 1832704207340000	11/27/2018	\$195.86
3	B.K.	4/4/2019	Medicaid 1909414423670000	4/9/2019	\$195.86
4	B.K.	4/16/2019	Medicaid 1910605155170000	4/23/2019	\$195.86
5	F.M.	9/17/2019	Medicare 310219260783390	10/1/2019	\$241.98
6	H.C.	7/29/2020	Medicare 310220211242860	8/12/2020	\$246.92
7	G.S.	2/11/2021	Medicare 310221042640160	2/25/2021	\$246.92
8	B.W.	12/9/2021	Medicare 310221343297130	12/27/2021	\$246.92

All in violation of Title 18, United States Code, Sections 1347 and 2.

COUNT NINE

(Conspiracy to Commit Unlawful Distribution of Controlled Substances)

- 29. Paragraphs 1 through 8 are incorporated by reference as if fully set forth herein.
- 30. From in or about August 2018, continuing up to and including in or about December 2021, the exact dates to the Grand Jurors unknown, in the County of Surry, in the Middle District of North Carolina, and elsewhere,

WENDELL LEWIS RANDALL; co-conspirators 1 ("CC1"), CC2, CC3, and CC4, all nurse practitioners at NIT at various times throughout the conspiracy; CC 5, a counselor at NIT; and others known and unknown to the Grand Jury, conspired and agreed with each other to knowingly and intentionally distribute and dispense oxycodone, oxymorphone, hydrocodone, amphetamine, and morphine, Schedule II controlled substances, knowing that such substances were not for a legitimate medical purpose and outside the usual course of professional practice in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C).

31. It was a part of the conspiracy that CC1, CC2, CC3, CC4, and CC5 would perform office visits with patients at NIT to create the illusion of legitimate medical care such that WENDELL LEWIS RANDALL could write prescriptions for controlled substances without a legitimate medical purpose and outside the usual course of professional practice.

All in violation of Title 21, United States Code, Section 846.

COUNTS TEN THROUGH THIRTY-SEVEN (Unlawful Distribution of Controlled Substances)

32. Paragraphs 1 through 8 are incorporated by reference as if fully set forth herein.

33. On or about the dates specified as to each count below, in the County of Surry, in the Middle District of North Carolina, WENDELL LEWIS RANDALL, did knowingly and intentionally and without authority distribute and dispense a mixture and substance containing a detectable amount of the Schedule II controlled substances listed below, without a legitimate medical purpose and outside the usual course of professional practice:

Count	Patient Initials	On or About Date Prescription Written	Drug	Quantity of Pills
10	L.B.	12/11/2018	Oxycodone	28
11	L.B.	12/11/2018	Oxycodone	112
12	L.B.	3/11/2019	Oxycodone	126
13	L.B.	3/11/2019	Methylphenidate	56
14	L.B.	8/20/2020	Oxycodone	63
15	L.B.	8/20/2020	Methylphenidate	28
16	S.R.	12/17/2018	Oxycodone	195
17	B.K.	4/18/2019	Oxycodone	112
18	K.S.	4/22/2019	Oxycodone	84
19	K.S.	4/22/2019	Oxymorphone	56
20	K.S.	7/15/2019	Oxycodone	112
21	K.S.	7/15/2019	Oxymorphone	56

22	L.H.	5/30/2019	Oxycodone	84
23	L.H.	5/30/2019	Amphetamine	28
24	L.H.	6/27/2019	Oxycodone	112
25	L.H.	6/27/2019	Amphetamine	28
26	A.R.	9/18/2019	Hydrocodone	42
27	T.K.	7/30/2019	Oxycodone	56
28	T.K.	7/30/2019	Oxymorphone	28
29	R.C.	10/3/2019	Oxycodone	150
30	D.K.	10/24/2019	Oxycodone	168
31	D.K.	10/24/2019	Oxymorphone	56
32	D.C.	12/4/2019	Oxycodone	42
33	D.C.	12/4/2019	Fentanyl	5
34	D.C.	6/4/2020	Oxycodone	56
35	D.C.	6/4/2020	Morphine	56
36	S.H.	2/27/2020	Amphetamine	56
37	S.H.	8/13/2020	Amphetamine	28

All in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C) and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATION

14

- 1. The allegations contained in this Indictment are realleged and by this reference fully incorporated herein for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 982(a)(7), Title 21, United States Code, Section 853(a), and Title 28, United States Code, Section 2461(c).
- 2. Upon conviction of one or more of the offenses charged in Counts One through Eight of this Indictment, the defendant, WENDELL LEWIS RANDALL, shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of such offense.
- 3. Upon conviction of one or more of the offenses alleged in Counts Nine through Thirty-Seven of this Indictment, the defendant, WENDELL LEWIS RANDALL, shall forfeit to the United States, pursuant to Title 21, United States Code, Section 853(a), all right, title and interest in and to any property constituting, or derived from, any proceeds obtained, directly or indirectly, as a result of such violation; and any property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, such violation.
- 4. The property subject to forfeiture may include, but shall not be limited to, a money judgment in an amount to be determined, representing the value of the proceeds or property subject to forfeiture as a result of such offense.

5. If any of the property described above as being subject to forfeiture as a result of any act or omission of the defendants cannot be located upon the exercise of due diligence, has been transferred or sold to or deposited with a third person, has been placed beyond the jurisdiction of the Court, has been substantially diminished in value, or has been commingled with other property which cannot be divided without difficulty, it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of said defendants up to the value of the above forfeitable property.

All in accordance with Title 18, United States Code, Section 982(a)(7), Title 21, United States Code, Section 853, Rule 32.2, Federal Rules of Criminal Procedure, and Title 28, United States Code, Section 2461(c).

DATED: September 25, 2023

SANDRA J. HAIRSTON United States Attorney

BY: REBECCA A. MAYER

Assistant United States Attorney

A TRUE BILL:

FOREPERSON